APR - 3 2001

K010792

DIGITEC MEDICAL SERVICE CORPORATION
510 (K) SUMMARY

Name:	Digitec Medical Service Corporation
Address:	465 Maltbie Street, Suite 407, Lawrenceville, GA. 30045
Phone:	770-995-0050
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Contact person:	James McGinty
Date of preparation:	March 15, 2001
Name of Device:	Mammo•*graph*
Trade:	Mammo•*graph*
Common:	Graphic image overlay
Classification name:	Accessory to Mammographic X-Ray System Per 21 CFR SEC 892.1710

Legally marketed device to which we are claiming equivalence:

Generic: All brands of mammography systems.
For clarification and continuity we have referenced the GE DMR X-ray Mammography System, K913418, throughout our explanation.

Description of Device

The mammo•*graph* is a clear vinyl sheet placed over a breast image on the viewbox. Printed on it are various markings and indicators for operator reference.

AEC position indicators identical to those appearing on the compression paddle are reproduced on the mammo•*graph*. A line identifies the center of the x-ray system and the image receptor. Throughout the mammo•*graph* is a grid pattern calibrated in centimeters.

There are mammo•*graph*s for the 18 x 24 and 24 x 30cm film formats; and for right and left images.

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Intended Use of the Mammo•*Graph*

The mammo•*graph* is an image overlay used to evaluate positioning and exposure techniques in film/screen mammography. It also provides an x-y coordinate system for referencing areas of interest within the image. The mammo•*graph* is used on the viewbox directly over a breast image.

Non-Clinical Testing

Discussion

The mammo•*graph* has the same AEC detector position indicators as the compression paddle. This allows the technologist to review all possible AEC positions relative to the **image**. The AEC detector indicators drawn on the mammo•*graph* must align with the indicators drawn on the compression paddle. This was tested by two (2) methods:

1. Physical Alignment:
Alignment of mammo•*graph* indicators compared to the indicators on the compression paddle. To verify alignment, the compression paddle from the mammography system is removed and placed over the mammo•*graph*. Visual inspection demonstrates that the size, shape and placement of the AEC indicators match those on the compression paddle.

2. Radiographic Alignment:
Any point on the breast image, located by the mammo•*graph* must match a corresponding point on the compression paddle.

Methods:

- Place a coin on the compression paddle directly over the center of the 2nd photo detector indicator.
- Place compression paddle 4.5 cm above bucky surface.
- With film/cassette in the bucky, image the coin.
- Place the processed film on the viewbox aligned with the mammo•*graph* over it, the coin will appear in the center of the 2nd photo detector indicator on the mammo•*graph*.

Conclusions:
Size shape and position of the indicators on the mammo•*graph* being identical to those on the compression paddle insure accuracy equivalent to the predicate device. Our testing confirms accuracy within the allowable misalignment of the compression paddle and image receptor; 1% SID

Technological Characteristics:

The technological characteristics of the mammo•*graph* are the same as the predicate device relating to AEC position indicators.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. James McGinty
President
Digitec Medical Service Corp.
465 Maltbie Street, Suite 407
LAWRENCEVILLE GA 30045

Re: K010792
Mammo-Graph
Dated: March 15, 2001
Received: March 16, 2001
Regulatory Class: II
21 CFR §892.1710/Procode: 90 IZH

Dear Mr. McGinty:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

STATEMENT OF INDICATIONS OF USE

The mammo•*graph* is an image overlay used by the technologist and radiologist to evaluate positioning and exposure techniques in film/screen mammography. It also provides a x-y coordinate system for referencing areas of interest within the image. The mammo•*graph* is used on the viewbox directly over a breast image.

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010792